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10/562,925	12/30/2005	Young-Taek Sul	P57712	3683

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ROBERT E. BUSHNELL
1522 K STREET NW
SUITE 300
WASHINGTON, DC 20005-1202

EXAMINER	
AUSTIN, AARON	
ART UNIT	**PAPER NUMBER**
1794	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,925	SUL, YOUNG-TAEK	
	Examiner	Art Unit	
	AARON S. AUSTIN	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-8,15-17,19 and 20* is/are rejected.

7)☒ Claim(s) *9-14 and 18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the present amendment has added language limiting the composition to percent by weight. The specification does not appear to provide support for these limitations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-8, 15, 17, 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vizethum et al. (DE 4407993) in view of Kamiya et al. (JP 2003-268481 – see the enclosed computer translation), and further in view of the teachings of

Chang et al. (KR 9208348 – abstract enclosed), and still further in view of Hall et al. (WO 00/72777 A1) and Kruger (DE 2135004).

Vizethum et al. teach an implant comprising a titanium or titanium alloy implant body (2, 4) having a suitable oxide layer (30, 31) formed by anodic oxidation.

Vizethum et al. do not teach the suitable oxide layer as being a magnesium titanate oxide film formed by low voltage dielectric breakdown anodic oxidation.

Kamiya et al. teach a composite suitable for use in implantation formed by sintering a mixture of magnesium oxide and titanium. Sintering these constituents is expected to produce magnesium titanate oxide (see the enclosed abstract for KR 9208348 for example). Therefore, as Kamiya et al. clearly teaches a composite comprising magnesium titanate oxide provides the advantage of a suitable oxide for an implant, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to use magnesium titanate oxide as the oxide coating of Vizethum et al.

Vizethum et al. in view of Kamiya et al. and Chang et al. teach anodic oxidation to form an oxide but do not necessarily teach all the claimed steps of the process for preparation of the implant as claimed. More particularly, they do not teach both irradiation with UV light and anodic oxidation in an electrolyte solution.

Hall et al. teach a titanium implant having a relatively thick oxide layer formed by anodic oxidation in an electrolyte solution at a voltage of 150 to 400 volts (page 8, lines 36-39; page 10, lines 1-8). Soaking in an aqueous solution precedes the anodic oxidation process. The process may be used to produce an oxide layer of 1-20 microns

(page 13, lines 9-11). Therefore, as Hall et al. clearly teach anodic oxidation in an electrolytic solution provides the advantage of a desirable porous oxide for coating a titanium implant, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to form the oxide layer of Vizethum et al. using this method.

Kruger teaches use of UV irradiation in conjunction with anodic oxidation of metals such as titanium. Therefore, as Kruger clearly teaches UV irradiation in conjunction with anodic oxidation of titanium provides the advantage of a process performed at reduced potential, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to perform anodic oxidation as taught by Hall et al. in conjunction with UV radiation to form the implant of Vizethum et al. Regarding the duration of irradiation, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the duration of irradiation for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Vizethum et al. in view of Kamiya et al. and Chang et al. do not necessarily teach an upper porous layer and a lower barrier layer.

Hall et al. teach formation of different areas within an oxide layer formed by anodic oxidation may include an upper layer of open pores and a lower barrier layer of closed pores (page 7, lines 25-35). Therefore anodic oxidation as taught by Hall et al. and/or Vizethum et al. is expected to produce the claimed layers.

Please note, claims 1, 19, and 20 include product by process language (e.g., formation by low voltage dielectric breakdown anodic oxidation). The above arguments establish a rationale tending to show the claimed product is the same as what is taught by the prior art. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 227 USPQ 964,966. Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983), MPEP 2113.

Regarding claims 5 and 6, the thickness of the oxide layer taught by Vizethum et al. is in the range of 200 to 500 nm (claim 1).

Regarding claim 8, it would be obvious to one of ordinary skill in the art at the time of the claimed invention to use an electrolyte solution of single or mixed composition containing magnesium to form the oxide of Vizethum et al. as it would allow for the formation of the magnesium titanate oxide of Kamiya et al. as outlined above.

Allowable Subject Matter

Claims 9-14 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments, see the Remarks, filed 1/22/08, with respect to the objection to the Abstract and the rejection of claims 3 and 16 under 35 USC 112, second paragraph have been fully considered and are persuasive in light of the present amendments. The objection and rejections have been withdrawn.

Applicant's arguments filed 1/22/08 with respect to the rejections over prior art have been fully considered but they are not persuasive.

First, Applicant argues the rejection is improper as Kamiya et al. teach a titanium radical composite strengthened by magnesium oxide particles in a matrix comprising a titanium material to form a composite rather than the combination of titania and magnesia particles used to produce $MgTiO_3$ on sintering as taught by Chang et al. As such, it is argued that the Examiner unreasonably regarded the titanium composite in which the magnesium oxide is distributed in Kamiya et al. as magnesium titanate.

However, a combination of titanium as a radical with magnesium oxide (magnesia) is expected to form a combination of titania and magnesia in some amount at the molecular level due to the interaction between molecules. Even further, upon

sintering any distinction between the parts of the composite become further indistinguishable and $MgTiO_3$ is expected as a product as taught by Chang et al. The argument is therefore unconvincing.

Second, Applicant argues the present specification provides for a magnesium titanate oxide film structure different from the $MgTiO_3$ structure formed by the combination of references used in the rejection. The argument points to paragraph [0022] of the present specification which provides for a film formed of several separate layers. The argument concludes without support that Vizethum et al. and Kamiya et al. cannot produce such a structure.

However, this argument is unsupported and not commensurate with the claims and is therefore unconvincing.

Third, Applicant argues there is no expectation of success in combining Vizethum et al. with Kamiya et al.

However, Vizethum et al. teach an implant comprising a titanium or titanium alloy implant body (2, 4) having a suitable oxide layer (30, 31). Kamiya et al. teach a composite suitable for use in implantation formed by sintering a mixture of magnesium oxide and titanium. Sintering these constituents is expected to produce magnesium titanate oxide (see the enclosed abstract for KR 9208348 for example). Where on reference teaches an oxide layer for an implant is desirable and the other reference teaches a particular composition suitable as an oxide coating for an implant, there is an expectation of success as the references directly correlate in function and structure.

As to the argument that appears to be presented suggesting the additional references do not teach incorporation of magnesium in anodic oxidation such that one of ordinary skill in the art would know to use such a process in forming the implant of Vizethum et al. in view of Kamiya et al., the teachings of Hall are not limited to formation of titanium oxide layers that do not include a cation. If fact, an exemplary oxide layer is formed including carbon (page 7, lines 36 to page 8, line 2). Therefore the Hall reference in no way teaches away from using anodic oxidation to form a titanium oxide coating including a cation.

Fourth, Applicant argues the prior art does not suggest or teach the desirability of forming a magnesium titanate oxide film. In particular, Applicant argues Vizethum et al. teach a metal of the oxide coating is also a metal in the underlying substrate and thus does not permit for formation of a magnesium titanate oxide. Applicant points to a translation that has not been made of record for support.

However, if magnesium titanate oxide overlies a titanium substrate, the metal titanium is common to both the coating and the substrate. As such, the argument appears to be moot and is therefore unconvincing.

Fifth, Applicant argues the ordinary skilled person in the art would change the anodic oxidation of Vizethum et al. into the sintering method of Kamiya.

However, this argument is unconvincing as it's unsupported. Further, there appears to be no reason preventing one of ordinary skill in the art from using the anodic oxidation as taught by Vizethum et al. to form the compound forming the film taught by Kamiya et al. in view of Chang et al. That is to say, as Kamiya et al. in view of Chang et

al. teach $MgTiO_3$ is a desirable implant coating, it is not beyond the skill of one in the art to use the anodic oxidation method of Vizethum et al. and/or Hall et al. to form this desirable coating. Thus the arguments are unconvincing.

Sixth, Applicant argues that the formation of the upper porous layer and the lower barrier layer provides for unexpected results sufficient to overcome the obviousness rejection.

However, this argument is not convincing as Hall et al. teach formation of different areas within an oxide layer formed by anodic oxidation may include an upper layer of open pores and a lower barrier layer of closed pores (page 7, lines 25-35). Therefore anodic oxidation as taught by Hall et al. and/or Vizethum et al. is expected to produce the claimed layers.

Further, to be given substantial weight in the determination of obviousness or nonobviousness, evidence of secondary considerations must be relevant to the subject matter as claimed, and therefore the examiner must determine whether there is a nexus between the merits of the claimed invention and the evidence of secondary considerations. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 305 n.42, 227 USPQ 657, 673-674 n. 42 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986), see MPEP 716.01(b). In the present case, the evidence submitted by applicant does not directly link the existence of layers as claimed to the osseoinductive properties and mechanical strength. Thus the arguments are not convincing.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON S. AUSTIN whose telephone number is (571)272-8935. The examiner can normally be reached on Monday-Friday: 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (571) 272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John J. Zimmerman/
Primary Examiner, Art Unit 1794

ASA